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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,795	01/28/2000	Maren Watkins	2314-179	2673

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EXAMINER
BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/493,795	WATKINS ET AL.	
	Examiner	Art Unit	
	Gabriele E. BUGAISKY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,8,9 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *39* is/are allowed.

6)☒ Claim(s) *2, 8-9, 40-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The amendment of 3/19/2003 is acknowledged. Claims 3-8 and 10-38 have been cancelled and new claims 40-41 have been submitted. Claims currently pending are 1-2, 8-9 and 39-41.

Specification

The objection to the specification is withdrawn, based upon the amendment.

Claim Objections

Claim 2 is objected to because of the following informalities: It recites formula I without reference to SEQ ID NO:1 . Appropriate correction is required.

The objection to claims 3 and 39 is withdrawn, based upon the amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim2, 9 and 40-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for derivatives of SEQ ID NO:5 wherein a single amino acid is replaced, does not reasonably provide enablement for the full scope of derivatives which include substitution at any site extent for Xaa3.. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. First, it must be pointed out the derivates of SEQ ID NO:5 include non-elected subject matter. Second, no working examples of any derivatives have been provided. The claims include any derivatives of SEQ ID NO:5 , a large number of which may not be active as conotoxin. Applicants have not taught to what extent one may change the primary structure and still allow the peptide to fold properly. A large number of derivatives would be expected to sterically hinder formation of the correct disulfide linkages and one has been given no tools to reasonably predict which (or how many ammo acids) may be altered. With respect to claim 40, Applicants state what such substitutions may be, but these recitations are seen as non-limiting.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 9 remain rejected and claims 40-41 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment to claim 2 is acknowledged.

The claim currently reads as follows: "A substantially pure α-conotoxin peptide of generic formula I selected from the group consisting of:

Ala-Cys-Cys-Ser-Asp...(SEQ ID NO:5);

and a derivative thereof,

wherein Xaa3 is Trp(D or L)... and the C-terminus contains a . . . group".

"A derivative thereof" is confusing as it is unclear whether derivative is of formula I or SEQ ID NO:5, If the latter is intended, it is suggested that the claim be amended to recite e.g., "and a derivative of SEQ ID NO:5". It also is unclear which Xaa3 is Trp or a Trp analog- it is the Xaa3 of SEQ ID NO:1 or that of SEQ ID NO:5

Claim 40 is further confusing in that it recites that a TRP residue is substituted with any unnatural aromatic amino acid; SEQ ID NO:% has but a single Trp. If Xaa3 of claim 2 refers to SEQ ID NO:5, it is noted that that claim specifies that the derivative have Trp or a specific Trp analog; thus, how could one substitute at that position?.

Claims 9 and 40-41 are included in this rejection as they depend from claim 2 and do not clarify the ambiguity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim2 is rejected under 35 U.S.C. 102(a) as being anticipated by Blom *.et al.*. The reference provides in Figure 6a the sequence of *Bodo saltans* ND5 which comprises the sequence CCFFVFCFYGC beginning at amino acid 131. The reference can be considered anticipatory for the claimed subject matter because this protein can be considered a derivative of SEQ ID NO:5 wherein the Xaa3 of the sequence is Y.

The rejection of claims 1 and 8 under 35 U.S.C. 102(b) as being anticipated by Olivera *et al.*(5514774) is withdrawn, based upon the amendment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1 and 8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5514774 is withdrawn, based upon the amendment

Conclusion

Claim 39 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-

4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

July 18, 2003